COMMITTEE ON GOVERNMENT REFORM

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MEDIA ADVISORY

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Government Reform Committee to Examine Cancer Clinical Trial Participation Rates

Only 3% Enroll in Clinical Trials When 20% Are Eligible
More Participants Are Essential for Improving Cancer Treatment

What: Government Reform Committee oversight hearing:
"Harnessing Science: Advancing Care by Accelerating the Rate of Cancer Clinical Trial Participation"

When: THURSDAY, May 13, 2004, 10:00 a.m.

Where: ROOM 2154, RAYBURN HOUSE OFFICE BUILDING

Background:

The purpose of this hearing is to examine the status of efforts to bring innovative cancer treatments to public and to discuss how to change the face of cancer into a more chronic and treatable disease. The hearing will consider the various factors contributing to low accrual of adult patients in cancer clinical trials and what efforts are being taken to obtain reasonable participation levels to better provide more treatment options to cancer patients.

Over half a million Americans die of cancer each year - more than 1,500 people per day - making cancer the second leading cause of death in the United States. Roughly 1,285,000 new cancer cases are diagnosed in the country each year. From 1990-2002 the Food and Drug Administration (FDA) approved only 71 cancer drugs. However, there are currently an estimated 400 new therapeutics available to be tested. In order for FDA to approve these new drugs to provide more treatment options to patients, several cancer clinical trials must be conducted.

As of July 2002, there were about 1,700 active cancer clinical trials, of which 1,200 are sponsored or conducted by National Cancer Institute. It is generally

recommended that 5,000 patients or more be enrolled in order to meet criteria for new drug approval. However, only 3% of adults nationwide enroll in clinical trials when up to 20% are eligible, a number much lower than needed to answer pressing cancer treatment questions.

Clinical trials are essential for determining safe and effective therapies in modern medicine. The combination of early detection of cancer and the application of new treatment developed through clinical research is responsible for the significant improvement in current cancer survival rates. Trials allow doctors and researchers to gain information about the benefits, side effects, and possible applications of new drugs, as well as different combinations, doses, and new indications of existing drugs. As the fundamental understanding of cancer increases, a growing number of new opportunities will require increasing numbers of adults to agree to participate in a clinical trial.

The Food, Drug, and Cosmetic Act requires FDA to ensure new drugs developed by pharmaceutical companies are safe and effective. Under this law, FDA physicians, scientists and other staff first review animal testing data submitted by drug developers, with the goal of determining if the drug is safe enough to test in human clinical trials. Clinical trials are carried out following very strict scientific guidelines. FDA then reviews the results of four distinct phases of human clinical trials; in each, statistical benchmarks must be met prior to moving on to the next phase.

In order for scientists and oncologists to make accurate conclusions about an experimental new drug's effects, clinical trials require the participation of numerous cancer patients. The amount of time taken to gather these participant groups is substantial, but necessary. Further, research has shown that clinical trial participants nearly always receive equivalent or better care than those receiving standard treatments, despite the experimental nature of these investigational treatments. Clinical trials often offer patients advanced treatment that would otherwise be unattainable. Yet, only 3% of adults nationwide enroll in clinical trials.

A number of factors contribute to low adult participation in cancer clinical trials in the U.S. The ability to recruit adult participants for future trials will partly depend on patient and physician education, which is lacking. A full 85% of cancer patients are unaware that clinical trials even exist, and of those who are aware, most harbor misconceptions about clinical trials and the manner in which they are conducted. Enrollment could increase if more physicians participated in clinical trials and recommended them as a treatment option to cancer patients. The vast majority of cancer patients therefore fail to consider clinical trials when reviewing their treatment options, resulting in the low participation by adults with cancer.

Clinical trials are essential for improving outcomes in cancer patients. This hearing will examine the different scientific, logistical and financial realities that interact to impede reasonable participation in adult trials. Witnesses at the hearing will provide an update on the status of new cancer therapies in the pipeline and how to resolve the barriers to adequate adult enrollment in clinical trials. By obtaining reasonable participation levels and creating more trials to test new therapies, cancer can evolve into a more treatable and chronic disease.

WITNESSES

Panel One:

Dr. Michaele Christian, Associate Director, Division of Cancer Treatment and Diagnosis, Cancer Therapy Evaluation Program, National Cancer Institute

Dr. Richard Pazdur, Director, Division of Oncology Drug Products, Center for Drug Evaluation and Research, Food and Drug Administration

Panel Two:

Dr. Andrew Pecora, Chairman and Director, The Cancer Center, Hackensack University Medical Center

Dr. Robert Comis, President and Chair, Coalition of National Cancer Cooperative Group

Ms. Ellen Stovall, President and Chief Executive Officer, National Coalition for Cancer Survivorship

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